K982803

NOV 13 1998

Premarket Notification 510(k) Summary [807.92]

for

CARDIAC TELECOM CORPORATION's

"HEART*Link II*"

[ECG Arrhythmia Detector and Alarm System]

Prepared on
August 1, 1998
[807.92(a)(1)]

cardiac telecom corporation

We Don't Miss a Beat!
503 Braddock Ave. Turtle Creek, PA 15145
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[A Division of Telemed Technologies, International]

10. 510(k) Summary:

10.1. Company Name and Contact Person:

Cardiac Telecom Corporation, Inc.
503 Braddock Avenue
Turtle Creek, PA 15145

412.824.6600 (Voice)
412.824.4225 (FAX)

LEE G. DENEAULT
[Director of Operations]

10.2. Name of the Device:

Proprietary Name:
HEARTLink, Model II

Common or Usual Name:
ECG Arrhythmia Detection and Alarm System

Classification Name:
Radio frequency physiological signal transmitter and receiver (21 C.F.R. § 870.2910)

Telephone electrocardiograph transmitter and receiver (21 C.F.R. § 870.2920)

Arrhythmia detector and alarm (21 C.F.R. § 870.1025)

10.3. Predicate or Legally Marketed Devices:

- **HEARTLink I (K934913)**
  Cardiac Telecom Corporation (Turtle Creek, PA)
- **King of Hearts (K880626)**
  Instromedix, Inc (Hillsboro, OR)
- **Aegis (K843503)**
  Medical Concepts, Inc (Gibbsboro, NJ)

10.4. Device Description:

The HEARTLink II System receives and processes radiofrequency encoded transmitted ECG signals on the Tele-Link monitoring unit. Abnormal ECGs and arrhythmias detected by the Tele-Link can be displayed on an optional video display monitor, while being simultaneously transmitted through standard telephone lines to a remote Central Station. The Central Station, located within health care institution or patient monitoring facility, is where an *alarm* is sounded and the ECG is again displayed for the review of medical personnel. The Central Station system has four dedicated phone lines and can provide remote monitoring of ECG data received from 30 individual Tele-Links. A total of 30 patients can be monitored at one time by a single one Central Station.

10.5. Intended Use:

The HEARTLink II System is intended to provide cardiac monitoring from a low-risk patient's home

to a central monitoring facility pursuant to physician prescription.

10.6. Technological Characteristics:

The HEARTLink II System is a microprocessor-based ECG arrhythmia detection and alarm system. The HEARTLink II is substantially equivalent to marketed ECG monitoring systems with arrhythmia detection capabilities, that have the same intended use and have received 510(k) premarket notification clearance from FDA (K880626 and K843503). The HEARTLink II is also technically equivalent to the *hospital-based* version of the HEARTLink I System (a.k.a. The HEARTrac System) that has already received clearance by the FDA as an arrhythmia detector and alarm system. The HEARTLink II System is intended for use in a *low-risk patient's home* environment and with the exception of a name change and a minimal change to the non-physiological information in the database management software is identical to the HEARTLink I System. The HEARTLink I was approved for use by the FDA on June 5, 1995 (K934913).

10.7. Summary of Performance Data:

Bench Testing:

The HEARTLink I System (in K934913) complied with all safety, emissions, and effectiveness standards under the FDA's MDS 201-0004, the

FCC's Parts 15 and 68 Rules, and the draft version of the AAMI EC-13-R-4/91 standards. The FDA's MDS 201-0004 standard has since been updated with the current version of the EMC Directive (EN 60601-1-2) and the draft of the AMMI standard has been adopted as a standard (with minimal changes). The FCC's Parts 15 and 68 have not changed since K934913. Since the HEARTLink II is technically equivalent to the HEARTLink I System, the compliance to the draft of the AAMI and the FCC's standards still apply. The HEARTLink II System, however, was safety and emissions re-tested and now complies with the current EMC Directive.

Clinical and Healthy Volunteers Trials:

Since the HEARTLink II System's intended environment for use is in the home of low-risk patients, this new environment raised following two safety and effectiveness issues:

- *Would the patient be able to effectively use the HEARTLink II System in the home environment (Usability Issue).*

- *Would the ECG data be able to be accurately transmitted to the Central Monitoring facility (Transmissability Issue).*

To test these two safety and effectiveness issues, two studies were designed. To test the Usability Issue, clincal trials were done at Saint Francis Medical Center (Pittsburgh, PA) and at Washington

Center Hospital (Washington, DC). The results of this study determined that the HEARTLink II System is "as usable" as the predicate Event Recorder System. To test the "Transmissability Issue", healthy volunteers were to wear both the HEARTLink II System and the predicate for a total of four days. Data collected simultaneously on these two systems were transmitted to their appropriate Central Monitoring facilities and subsequently analyzed for transmission quality. The results of this study determined that the HEARTLink II System is capable of transmitting data with equal fidelity as its predicate Event Recorder System.

10.8. Conclusions:

The HEARTLink II System is substantially equivalent to the HEARTLink I, King of Hearts, and the Aegis ECG monitoring systems. Performance data collected in laboratory bench-testing and in both clinical and healthy volunteer trails demonstrated that there are no new safety and effectiveness questions raised by the modifications made to the currently marketed HEARTLink I System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 1998

Cardiac Telecom Corporation
c/o Mr. Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, DC 20004-1109

Re: K982803
HeartLink II (Arrhythmia Detector and Alarm System)
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: August 10, 1998
Received: August 11, 1998

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (If known): K982803

Device Name: HEARTLink II

Indications For Use:

1. Patients who have demonstrated a need for cardiac monitoring and are at low risk of developing primary ventricular fibrillation or sustained ventricular tachycardia.

2. Specific criteria for indications for use are as follows :

- *Patients with dizziness or lightheadedness*
- *Patients with palpitations*
- *Patients with syncope of unknown etiology*
- *Patients who require monitoring for non life-threatening arrhythmias, such as atrial fibrillation, other supra-ventricular arrhythmias, evaluation of various bradyarrhythmias and intermittent bundle branch block. This includes post operative monitoring for these rhythms*
- *Patients recovering from coronary artery bypass graft (CABG) surgery who require monitoring for arrhythmias*
- *Patients requiring monitoring for arrhythmia-inducing co-morbid conditions such as hyperthyroidism or chronic lung disease*
- *Patients with obstructive sleep apnea to evaluate possible nocturnal arrhythmias*
- *Patients requiring arrhythmia evaluation for etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation*

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Mark Mewe

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

Prescription Use ✓
(Per 21 CFR 801.109)

Over-The-Counter Use_____

510(k) Number_____

(Optional Format 1-2-96)